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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/576,712

05/15/2006

Christian Hesslinger

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34375 7590 01/07/2009
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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------------|--|
| Office Action Summary | Application No. 10/576,712 | Applicant(s) HESSLINGER ET AL. | |
| | Examiner MARCOS SZNAIDMAN | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on September 16, 2008.

Status of Claims

Amendment of claims 1, 4, 6, 11, 14-15, cancellation of claims 10, 16-18 and 23 is acknowledged.

Claims 1-7, and 11-15 are currently pending and are the subject of this office action.

Claims 1-7, and 11-15 are currently under examination.

Priority

The present application claims priority to International Application No. PCT/EP04/52725 filed 10/29/2004 and to foreign application No. EP20030024844 filed 10/31/2003.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment and/or New Rejections and/or Objections not

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Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Rejection necessitated by Amendment)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1-7 and 11-15 have been amended to recite the limitation: "consisting essentially of". However, a careful review of the specification and the claims, as originally filed, does not appear to lend support for the limitation: "consisting essentially of"; nor does it appear to have contemplated the exclusion of any particular ingredients or how to determine if they "materially affect" the claimed composition.

Claim Rejections - 35 USC § 103 (Maintained Rejection)

1) Claims 1-4 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over applicants own admission and Manning (US 2004/0087653, cited in

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prior office action) as evidenced by Schmid et. al. (WO2001/56551, cited in previous office action and cited by applicant).

The reasons for this rejection have been provided in the previous office action dated June 16, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant claims to have amended claims 1, 4 and 6, replacing the transitional phrase "comprising" for "consisting essentially of" in an attempt to limit the compounds that are essential for the desired activity: BH4 derivatives listed in claims 1, 4 and 6, and exclude others, except for excipients or other substances that are not considered essential for the biological activity, and thus being able to overcome the prior art, which requires BH4 derivatives and other essential active agents. However there is no record of any amendment in the response sent by applicant on the response dated 09/16/08.

Moreover, MPEP 2111.03, clearly states that: for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." Accordingly, this rejection would be maintained even if the proposed amendment had been made.

2) Claims 5, 7, 11-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over applicants own admission and Manning (US 2004/0087653, cited in

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prior office action) as evidenced by Schmidt et. al. (WO2001/56551, cited in previous office action and cited by applicant) as applied to claims 1-4 and 6 above, and further in view of Juturu et. al. (US 2004/0097467) or Rabelnik et. al. (US 6,544,994, cited in prior Office Action).

The reasons for this rejection have been provided in the previous office action dated June 16, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that in the Juturu reference L-arginine HCl does not have the effect that was provided by the L-arginine-silicate-inositol complex, hence it teaches away from using L-arginine HCl. Applicant also argues that the arginine-silicate-inositol complex is not part of the instant claims.

Examiner's response: according to Juturu et. al. the arginine-silicate-inositol complex is a source of arginine (see claims 44 and 45 and paragraph [0042], so it would have been obvious to the skilled in the art to replace the arginine-silicate-inositol complex with arginine which is generated in the body. Regarding L-arginine HCl, even though is not as effective as the above complex, is still effective, so it will be obvious to try to use arginine HCl for the treatment of COPD as taught by Juturu.

Applicant's arguments regarding the Rabelnik reference are not longer valid since the application is still examined as the claims read as "comprising".

Withdrawn Rejections and/or Objections

Claims 16-17 rejected under 35 U.S.C. 102(a).

Due to applicant cancellation of claims 16-17, the 102(a) rejection is now moot.

Rejection under 35 U.S.C. 102(a) is withdrawn.

Claims 10, 18 and 23 rejected under 35 U.S.C. 103(a).

Due to applicant cancellation of claims 10, 18 and 23, the 102(a) rejection is now moot.

Rejection under 35 U.S.C. 103(a) is withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
December 30, 2008

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612